

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,516	01/04/2002	Ashkan Imanzahrani	31505.0001	6624

7590 08/07/2003

Kevin D. McCarthy, Esq.
Hodgson Russ LLP
Suite 2000
One M&T Plaza
Buffalo, NY 14203-2391

EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
----------	--------------

1614

DATE MAILED: 08/07/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/037,516

Applicant(s)

IMANZAHRAI

Examiner

Cybille Delacroix-Muirheid

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 18, 20, 22 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16, 18, 20 and 22 is/are allowed.
- 6) ☒ Claim(s) 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Detailed Action

1. Claims 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Armellino et al., 5,972,916 (already of record) in view of Munari et al. (as explained by Applicant's specification page 12, lines 9-23).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

The following is responsive to Applicant's amendment received March 25, 2003.

No claims are cancelled. No new claims are added. Claims 16, 18, 20, 22 and 26 are currently pending.

The previous claim objection set forth in paragraph 1 of the office action mailed Nov. 20, 2002 is **withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 112, paragraph 2, set forth in paragraph 2 of the office action mailed Nov. 20, 2002 is **withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous rejection of claim 16 under 35 USC 103(a) set forth in paragraphs 3-5 of the office action mailed Nov. 20, 2002 is **withdrawn** in view of Applicant's amendment and the remarks contained therein.

However, Applicant's arguments traversing the previous rejection of composition claim 26 under 35 USC 103(a) set forth in paragraphs 3-5 of the office action mailed Nov. 20, 2002 have been considered but are not found to be persuasive.

Said rejection is maintained essentially for the reasons given previously in the office action mailed Nov. 20, 2002 with the following additional comment:

Applicant argues that the Munari reference fails to cure the deficiencies of the Armellino patent because Munari's results have shown only a limited set of cardiovascular responses to a limited set of autonomic in migraine sufferers who were not suffering from migraines during the clinical tests. Notwithstanding, Applicant has removed the limitation "and other associated symptoms" from claim 26 in order to allow the Examiner to no longer consider the relevance of the teaching of the Munari reference.

Additionally, with respect to the Examiner's comments concerning the dosage amounts, Munari uses a constant amount of pseudoephedrine in each individual tested. Furthermore, there is no suggestion to combine pseudoephedrine with other compounds. Therefore, Munari does not teach or even suggest that pseudoephedrine's efficacy is dependent on dosage amounts especially when used in combination with other drugs because Munari never studied the effect of pseudoephedrine with other drugs in migraine patients. Finally, Applicant contends that Munari is silent with respect to the appropriate amount of pseudoephedrine needed for relieving migraine symptoms.

Said arguments have been considered but are not found to be persuasive.

The Examiner respectfully submits that according to Applicant's explanation of the prior art to Munari et al., when migraine patients were administered pseudoephedrine, cardiovascular abnormalities were treated, namely lower blood pressure and postural hypotension. (please see page 12, lines 8-22).

With respect to Applicant's arguments regarding the "appropriate dosage amount of pseudoephedrine for relieving migraine symptoms", the Examiner respectfully submits that Applicant is arguing the effective amounts **functionally**, i.e. an effective amount to treat migraine symptoms. First of all, please note that claim 26 does not require "an effective amount" of pseudoephedrine. Claim 26 allows for any amount. Next, assuming that claim 26 did set forth "an effective amount", since the amounts would be claimed functionally, one of ordinary skill in the art would turn to the specification where Applicant describes the amount of pseudoephedrine that should be present in the claimed composition. However, Applicant has not clearly argued how this amount desired by Applicant is not disclosed or is distinguished over the amount disclosed in the prior art. Applicant has not specifically argued, on the record, how the claimed amounts of pseudoephedrine differ from the amounts of pseudoephedrine in the Munari reference. Absent such arguments, the amounts of pseudoephedrine in the prior art may be capable of treating migraine symptoms. Finally, as the claims are currently presented, the Examiner respectfully submits that, in view of Munari's significant results, the amounts used in the study are appropriate for treating some of the cardiovascular abnormalities found in patients who are migraine sufferers.

Moreover, claim 26 is a composition claim intended for the use of treating migraines in patients. However, please note that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the

Art Unit: 1614

claim. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). In this case, absent further evidence/arguments to the contrary, and since the claims allow for any amount of pseudoephedrine, the amount of pseudoephedrine in Munari would be capable of performing the intended use, i.e. treating migraine pain.

Finally, in addressing Applicant's argument that Munari does not disclose combining pseudoephedrine with other drugs, i.e acetaminophen, the Examiner respectfully maintains that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the migraine-treating composition containing acetaminophen of Armellino with the pseudoephedrine of Munari because one of ordinary skill in the art would reasonably expect the additive effect of the acetaminophen-containing compositions and the pseudoephedrine to be effective in treating migraine pain and associated symptoms. Moreover, one of ordinary skill in the art would reasonably expect pseudoephedrine to treat any cardiovascular abnormalities, i.e. a "functional disability", that the patients of Armellino may experience. Therefore, such a modification would have been motivated by the reasoned expectation of producing a composition for successfully and comprehensively treating a migraine and cardiovascular abnormalities associated therewith.

It is for these reasons that the rejection of claim 26 is maintained.

Allowable Subject Matter

Claims 16, 18, 20, 22 are free from the prior art because the prior art does not disclose or fairly suggest the claimed methods.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is 703-306-3227. The examiner can normally be reached on Tue-Thur. from 8:30 to 6:00. The examiner can also be reached on alternate Mondays .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725 The fax phone number for the organization where this application or proceeding is assigned is 703-308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Application/Control Number: 10/037,516

Page 7

Art Unit: 1614

CDM



Aug. 6, 2003

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1200

